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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,052	08/21/2001	David Gregory Kitchens	14291-68335	7380
23643	7590	05/17/2004		
BARNES & THORNBURG 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204				
EXAMINER ROBERT, EDUARDO C				
ART UNIT		PAPER NUMBER		
3732		10		

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/934,052

Applicant(s)

KITCHENS, DAVID GREGORY

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 12, 13 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10, 12 and 21-24 is/are rejected.
- 7) ☐ Claim(s) 13 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on April 9, 2004 has been entered.

Allowable Matter

The indicated allowability of claims 8-10, 12, and 21-24 is withdrawn in view of the reference to Gotfried (EP 0617927, cited by applicant on the IDS filed April 9, 2004).

Rejections based on the newly cited reference(s) follow.

Claim Objections

Claims 8-13 are objected to because of the following informalities:

In claim 8 there appears to exist an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "An instrument assembly" with the first orthopedic component and second orthopedic component being only functionally recited, i.e. "for percutaneously implanting an orthopaedic assembly having a first orthopaedic component and a second orthopaedic component...", thus indicating that the claim is directed to the subcombination, "An

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instrument assembly". However, throughout the body of the claim 8 and in dependent claim 12, applicant appears to positively recite the first and second orthopedic components as part of the invention, e.g. "wherein: said first orthopaedic component includes a bone screw ... said second orthopaedic component includes a bone plate" and in claim 12, "said bone screw has a flange secured thereto, said bone plate has a channel defined therein ...", thus indicating that the combination, instrument assembly and first and second orthopedic components, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination.

Applicant is hereby required to clarify to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 8-10, 12 and 13 will be considered as being drawn to the combination, instrument assembly and first and second orthopedic components.

Also, claims 21-25 appear to have a problem similar to the one of claim 1, specifically with regard to dependent claim 24. Thus, Applicant is hereby required to clarify to which, combination or subcombination, the claims are intended to be directed. **For examination purposes claims 21-25 would be considered as being drawn to the combination, instrument assembly and hip screw and bone plate.**

Appropriate clarification and/or correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

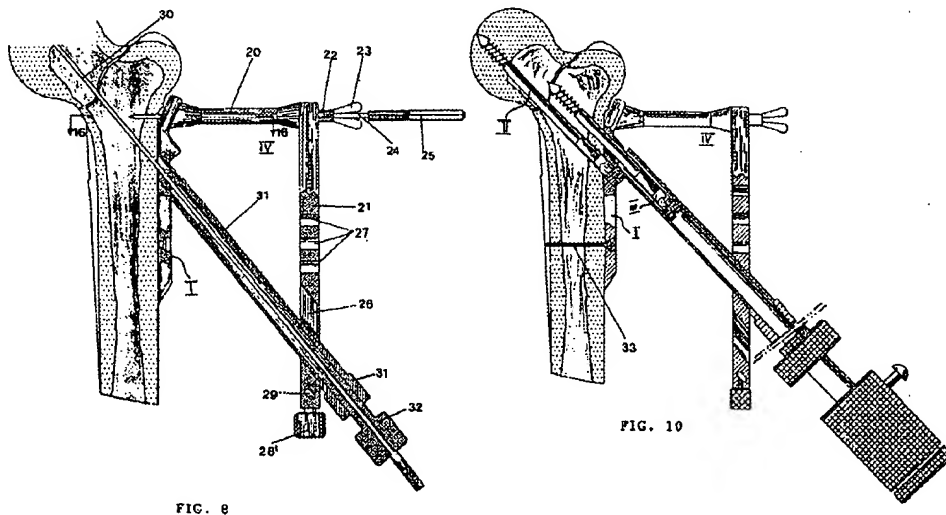
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A person shall be entitled to a patent unless –

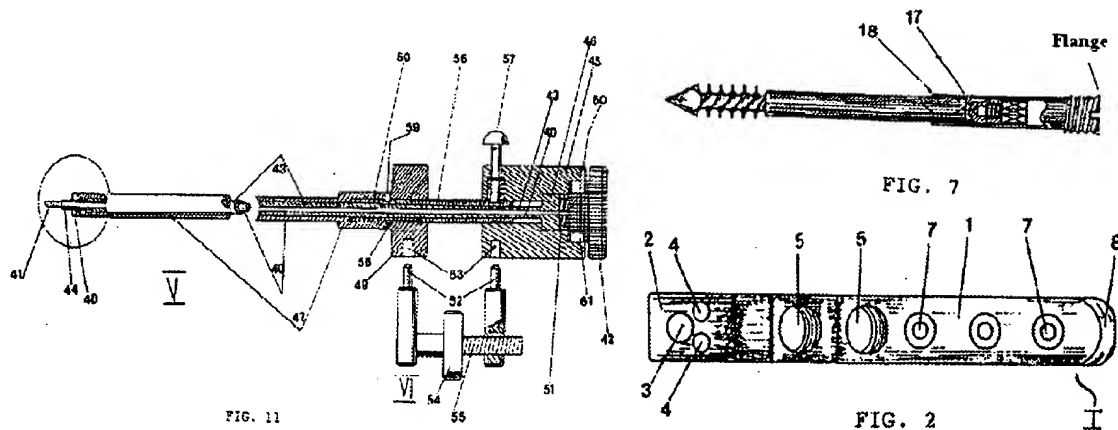
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10, 12 and 21-24, as understood, are rejected under 35 U.S.C. 102(b) as being anticipated by Gotfried (EP 0617927 cited by applicant on IDS filed on April 9, 2004).

Gotfried discloses an assembly, shown in Figures 8 and 10 below, comprising a first instrument or screw locating instrument V (see Figure 11 below) which is securable to an orthopedic component, e.g. a bone screw (see Figure 7 and col. 6, line 53, through col. 7, line 17). The first instrument has an alignment feature (first alignment feature), i.e. outer tube 47. It is noted that “alignment” is defined by *The American Heritage Dictionary of the English Language, Third Edition* 1992 by Houghton Mifflin Company as “Arrangement or position in a straight line”, thus the outer tube 47 can be considered an alignment feature since it positions or arranges the bone screw in a straight line as shown in Figure 10, below.



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The assembly further comprises a second instrument or plate locating instrument 22, i.e. a connecting screw, securable to another orthopedic component, e.g. a bone plate I having a screw thread 3 for receiving the connecting screw (see Figures 2, 8 and 10, above, and col. 5, lines 53-56). The second instrument has an alignment feature (second alignment feature), e.g. portion 20 (see Figure 8 above). It is noted that portion 20 position and guide the second instrument in a straight line as shown in Figure 8 (see col. 5, lines 53-55). Also, the assembly includes a third instrument 21 (see Figures 8 and 10, above). The third instrument 21 has an alignment feature (third alignment feature) which includes multiple bore or openings, e.g. bores 26 and 27 and a bore for the connecting screw, (see Figures 8 and 10, above). The third alignment feature cooperates ("cooperate" is defined by *The American Heritage Dictionary of the English Language, Third Edition* 1992 by Houghton Mifflin Company as "To work or act together toward a common end or purpose") with the first alignment feature, i.e. bore 26 cooperates with outer tube 47 as shown in Figure 10, and the second alignment feature, i.e. the bore for the connecting screw cooperates portion 20, so as to position the first instrument and second instrument in a predetermined position relative to one another. With regard to the functional

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language recited in claim 1, e.g. "so as to position said first instrument and said second instrument in a predetermined position..." and "so as to position said bone plate in contact with said bone screw during movement of said second instrument", it is noted that the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The first instrument has the "ability" or is "adapted to", i.e. capable of, be secured to the first orthopedic component prior to implantation or subsequent to implantation if one so desired. It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but **only requires the ability to so perform**. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. The bone screw (see Figure 7 above) has a flange secured thereto. The bone plate I has a channel defined therein, e.g. bores 5, 7, etc. (see Figure 2). With regard the recitation in claim 12, that the third alignment feature is further adapted to cooperate with, it is noted, as stated above, that the recitation that an element is "adapted to" perform a function is not a positive limitation but **only requires the ability to so perform**. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. In the instant case the third alignment feature has the ability to cooperate with the first and second alignment features in a way that the flange can be advanced into the channel and at the same time the second instrument with the bone plate secured to it is moved, i.e. the second instrument attached to the bone plate and third instrument can be move by one hand in the air and at the same time the bone screw can be inserted into the bone plate with the other hand.

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Allowable Subject Matter

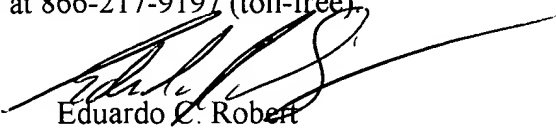
Claims 13 and 25, **as understood**, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333. The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.